

FELIZ S

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for FELIZ S (Escitalopram Oxalate Tablets)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Escitalopram is a selective inhibitor of serotonin (5-HT) re-uptake with high affinity for the primary binding site. It also binds to an allosteric site on the serotonin transporter, with a 1000 fold lower affinity. Escitalopram has no or low affinity for a number of receptors including 5-HT_{1A}, 5-HT₂, DA D₁ and D₂ receptors, α ₁-, α ₂-, β -adrenoceptors, histamine H₁, muscarine cholinergic, benzodiazepine, and opioid receptors. The inhibition of 5-HT re-uptake is the only likely mechanism of action explaining the pharmacological and clinical effects of escitalopram.

DOSAGE AND ADMINISTRATION: Safety of daily doses above 20 mg has not been demonstrated.

CONTRAINDICATION: Escitalopram is contraindicated in patients with known hypersensitivity to any component of the formulation of escitalopram or citalopram. Concomitant treatment with non-selective, irreversible monoamine oxidase inhibitors (MAO-inhibitors) is contraindicated due to the risk of serotonin syndrome with agitation, tremor, hyperthermia etc. The combination of escitalopram with reversible MAO-A inhibitors (e.g. moclobemide) or the reversible non-selective MAO-inhibitor linezolid is contraindicated due to the risk of onset of a serotonin syndrome. Escitalopram is contraindicated in patients with known QT interval prolongation or congenital long QT syndrome. Escitalopram is contraindicated together with medicinal products that are known to prolong the QT interval.

WARNINGS & PRECAUTIONS: Paediatric population, Paradoxical anxiety, Seizures, Mania, Diabetes, Suicide/suicidal thoughts or clinical worsening, Akathisia/psychomotor restlessness, Hyponatraemia, Haemorrhage, ECT (electroconvulsive therapy), Serotonin syndrome, St. John's wort, Discontinuation symptoms seen when stopping treatment, Sexual dysfunction, Coronary heart disease, QT interval prolongation, Angle-Closure Glaucoma.

DRUG INTERACTION: Pharmacodynamic interactions- Contraindicated combinations: Irreversible non-selective MAOIs, Reversible, selective MAO-A inhibitor (moclobemide), Reversible, non-selective MAO-inhibitor (linezolid), Irreversible, selective MAO-B inhibitor (selegiline), QT interval prolongation. Combinations requiring precautions for use: Serotonergic medicinal products, Lithium, tryptophan, St. John's wort, Haemorrhage, Alcohol, Medicinal products inducing hypokalaemia/hypomagnesaemia, Clonazepam, Etizolam. Pharmacokinetic interactions, Effect on the pharmacokinetics of other medicinal products.

ADVERSE REACTIONS: Thrombocytopenia, Anaphylactic reaction, Inappropriate ADH secretion, Decreased appetite, Increased appetite, Weight increased, Weight decreased, Hyponatraemia, Anorexia, Anxiety, Restlessness, Abnormal dreams, Libido decreased, Female: Anorgasmia, Bruxism, Agitation, Nervousness, Panic attack, Confusional state, Aggression, Depersonalisation, Hallucination, Mania, Suicidal ideation, Suicidal behaviour, Headache, Insomnia, Somnolence, Dizziness, Paraesthesia, Tremor, Taste disturbance, Sleep disorder, Syncope, Serotonin syndrome, Dyskinesia, Movement disorder, Convulsion, Psychomotor restlessness/akathisia, Mydriasis, Visual disturbance, Tinnitus, Tachycardia, Bradycardia, Electrocardiogram QT prolonged Ventricular arrhythmia including torsade de pointes, Orthostatic hypotension, Sinusitis, Yawning, Epistaxis, Nausea, Diarrhoea,

Constipation, Vomiting, Dry mouth, Gastrointestinal haemorrhages (including rectal haemorrhage), Hepatitis, Liver function test abnormal, Sweating increased, Urticaria, Alopecia, Rash, Pruritus, Ecchymosis, Angioedemas, Arthralgia, Myalgia, Urinary retention, Male: Ejaculation disorder, Impotence, Female: Metrorrhagia, Menorrhagia, Galactorrhoea, Male: Priapism, Fatigue, Pyrexia, Oedema.

Marketed BY:



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IN/FELIZ S 5,10,20 mg/FEB-21/03/ABPI

(Additional information is available on request)